

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AMICUS THERAPEUTICS US, LLC AND
AMICUS THERAPEUTICS, INC.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC. and
TEVA PHARMACEUTICALS, INC.;

Defendants.

C.A. No. 22-1461-CJB
ANDA CASE

(consolidated)

PROTECTIVE ORDER

WHEREAS Plaintiffs Amicus Therapeutics US, LLC and Amicus Therapeutics, Inc. (collectively “Plaintiffs”) and Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals, Inc., and Teva Pharmaceutical Industries Ltd., Lupin Ltd. and Lupin Pharmaceuticals, Inc., and Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively “Defendants”) assert that discovery in the above-captioned action (the “Action”) may involve the disclosure of certain documents, things, and information in the possession, custody, or control of the Parties or a non-party that constitute confidential and sensitive information in the form of trade secrets or other confidential and proprietary business, research, development, commercial, financial, personal, and/or technical information that must be protected in order to preserve the legitimate business interests of the parties or other persons;

WHEREAS the parties recognize that it may be necessary to disclose certain of the asserted confidential and proprietary information during the course of this Action and desire to

limit the disclosure and prevent the use of such information for any purposes other than the prosecution and defense of this Action;

WHEREAS the parties wish to enter the following Protective Order (hereinafter, the “Order”) to govern the disclosure, production, and use of information, documents, and tangible items in connection with this Action;

WHEREAS entry of this Order will advance this Action and prevent unnecessary dissemination or disclosure of such confidential and proprietary information; and

WHEREAS the parties have established good cause for entry of this Order, *see* Fed. R. Civ. P. 26(c), *Pansy v Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994);

NOW THEREFORE, pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, upon the stipulation and consent of the parties, by and through their respective undersigned counsel, and for good cause shown, the Court hereby **ORDERS**:

I. DEFINITIONS

(a) Confidential Information. The term “Confidential Information” shall mean any Discovery Material designated by a Producing Party (as defined below) as CONFIDENTIAL that the Producing Party claims in good faith embodies, constitutes, contains, reveals, relates to, or reflects information (i) that the Producing Party would not normally reveal to third parties except in confidence, or has undertaken with others to maintain in confidence, (ii) that the Producing Party believes in good faith is significantly sensitive, or (iii) protected by a right to privacy under federal or state law or any other applicable privilege or right related to confidentiality or privacy. Any information, document, or tangible item produced pursuant to District of Delaware Local Rule 26.2 prior to entry of this Order shall be treated as if it were designated CONFIDENTIAL INFORMATION.

(b) Highly Confidential Information. The term “Highly Confidential Information” shall mean any Discovery Material designated by a Producing Party as HIGHLY CONFIDENTIAL that the Producing Party claims in good faith constitutes: (i) proprietary commercial information related to market analysis, projections of market share, and sales and profits, if any, and any other future-looking commercial information related to sales of migalastat or dosage forms thereof; and (ii) competitive forward-looking financial or strategic commercial information, including forecasts and financial assumptions, the disclosure of which to another party or non-party could cause a competitive disadvantage to a Producing Party or could create a substantial risk of serious harm that could not be avoided by less restrictive means.

(c) Designated Material. The term “Designated Material” shall mean and include any information, document, or tangible item that has been marked as either CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, as provided herein. All information, documents, or tangible items to be produced that the Producing Party wishes to designate as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION must, prior to production to the Receiving Party (as defined below), be labeled by the Producing Party with the legend “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER” or “HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER,” as appropriate, on each page that the Producing Party believes constitutes or contains Confidential Information or Highly Confidential Information. Any item of “Designated Material” shall bear only one of the two confidentiality designations.

(d) Non-Confidential Information. The term “Designated Material” shall not include:

- i. Information that was or is in the public domain at the time of disclosure, not in violation of this Order;
- ii. Information that after disclosure is published or becomes part of the public domain, not in violation of this Order, and through no fault of a Receiving Party, but only after it is published or comes into the public domain;
- iii. Information that is in the possession of a Receiving Party without any confidentiality obligations at the time of disclosure, and that was received from a source that possessed the right to disclose without any such confidentiality obligations;
- iv. Information disclosed by a third party that is not subject to any confidentiality obligations at the time of the disclosure;
- v. Information discovered independently by the Receiving Party, not in violation of this Order; or
- vi. Information that was, is, or becomes expressly released from being DESIGNATED MATERIAL by the Producing Party or by order of this Court.

(e) Discovery Material. The term “Discovery Material” shall mean any Document (as defined below), material, item, testimony, or thing filed with or presented to the Court or produced, served, or generated during the discovery process, including, for example, exhibits, answers to interrogatories, responses to requests for admissions, responses to requests for production, subpoenas, declarations, affidavits, and deposition testimony or transcripts, and all copies, extracts, summaries, compilations, designations, and portions thereof.

(f) Document. The term “Document” shall mean every means of recording any form of communication or representation upon any tangible thing, including letters, numbers, words, pictures, sounds, or symbols, or combinations thereof, whether recorded by handwriting,

printing, photostatic or photographic means, magnetic impulse, tape, computer disk, CD-ROM or any other form of electronically stored information, and all other tangible things which come within the meaning of “writing” contained in Rule 1001 of the Federal Rules of Evidence, or within the meaning of “document” or “tangible thing” contained in Rule 34 of the Federal Rules of Civil Procedure.

(g) Producing Party. The term “Producing Party” shall mean any party to this Action or any third party, including its counsel, retained experts, directors, officers, employees, business partners, or agents, who produces any Discovery Material.

(h) Receiving Party. The term “Receiving Party” shall mean any party to this Action, including its counsel, retained experts, directors, officers, employees, business partners, or agents, who receives any Discovery Material in this Action.

(i) Scope. The scope of this Order shall be understood to encompass not only Confidential Information or Highly Confidential Information which is expressly designated as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL,” respectively, but also any information derived therefrom, including all copies, excerpts, and summaries thereof, whether partial or complete, as well as testimony and oral conversations which reveal all or part of that information. Further, information which becomes available to any party via inspection, measuring, analyzing or testing of any sample or thing designated as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” pursuant to this Order, or which is prepared or derived by utilizing information designated as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” and supplied under this Order, shall be considered “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL,” as the case may be, under this Order. The restrictions and obligations set forth in this Order shall not prohibit

discussion with any person or entity regarding any DESIGNATED MATERIAL if said person or entity already has legitimate possession thereof.

II. PROCEDURE FOR DESIGNATING MATERIALS

Documents, information, materials, pleadings, legal memoranda, expert statements and discovery responses, in whole or in part, may be designated as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” as follows:

(a) In the case of documents or any other tangible item produced, designations shall be made by placing the legend “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER” or “HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER” on each page, on the cover, or in a prominent place on the document prior to disclosure by the Producing Party;

(b) In producing original files and records for inspection, no marking need be made by the Producing Party in advance of the inspection;

(c) In the case of deposition testimony and transcripts or portions thereof, designation shall be made by the Producing Party either (i) on the record during the deposition, in which case the portion of the transcript of the designated testimony shall be bound in a separate volume and marked “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” by the reporter, or (ii) by captioned, written notice to the reporter and all counsel of record, given within fourteen (14) days after the reporter sends written notice to the deponent or the deponent’s counsel that the transcript is available for review, in which case all counsel receiving such notice shall be responsible for marking the copies of the designated transcript or portion thereof in their possession or control as directed by the Producing Party or deponent. Pending expiration of the fourteen (14) days, all parties and, if applicable, any third-party witnesses or attorneys, shall treat the deposition transcript as if it had been designated “HIGHLY CONFIDENTIAL.”

(d) When a party wishes to designate as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” its own materials produced by someone else, such designation shall be made:

i. within fourteen (14) days from the date that the party requesting the designation receives copies of such materials from the producing or disclosing entity; and (ii) by written notice to all parties to this Action and to the producing party, if such party is not a party to this Action, and identifying the materials to be designated with particularity (either by production numbers or by providing other adequate identification of the specific material). Such notice may be provided by e-mail. The parties receiving such materials agree to treat them as “HIGHLY CONFIDENTIAL” materials under this Protective Order until expiration of said fourteen (14) day period or until designation is made as set forth above within said fourteen (14) day period.

Except as otherwise provided in this Order or as otherwise stipulated or ordered, any information, document, or tangible item that qualifies for protection under this Order must be clearly designated before the material is disclosed or produced, subject to any provision of this Order allowing for later designation.

III. CONTESTING THE DESIGNATION

(a) No party to this Action shall be obligated to challenge the propriety of any designation by any Producing Party, and a failure to do so shall not constitute a waiver or in any way preclude a subsequent challenge in this or any other action to the propriety of such designation.

(b) Any party may contest a claim of confidentiality. Any party objecting to the designation of any Discovery Material as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” must give outside counsel of record for the Producing Party written notice of its reasons for the objection.

(c) If, after receiving written notice, the Producing Party refuses to change its confidentiality designation within seven (7) business days, the Receiving Party may move for an order changing or removing the designation. In the resolution of such matter, the burden of establishing confidentiality shall be on the party who made the claim of confidentiality, i.e., the Producing Party, but information designated as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” shall be deemed as such until the matter is resolved.

IV. RESTRICTION ON DISCLOSURE AND USE

(a) Confidentiality. Except as otherwise permitted by this Order, all material designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION and information derived from such Confidential Information or Highly Confidential Information (excluding information which is derived lawfully from an independent source) shall be kept confidential by the Receiving Party, shall not be used for any purposes other than the prosecution and defense of this Action, and shall not be given, shown, made available, discussed, or otherwise communicated in any manner, either directly or indirectly, to any person or entity except as otherwise permitted by this Order.

(b) Maintenance of Confidential Information. Confidential Information and Highly Confidential Information shall be maintained by the Receiving Party at a location and under circumstances to ensure that access is limited to those persons entitled to have access under this Order.

(c) A Producing Party is free to do whatever it desires with its own Confidential Information or Highly Confidential Information.

V. ACCESS TO DESIGNATED MATERIAL

(a) Access to information produced and designated as CONFIDENTIAL INFORMATION shall be available only to the following persons except as otherwise ordered by the Court or provided in this Order:

i. Three (3) in-house personnel of a party or a party affiliate who have responsibility for managing this Action, or who are assisting outside counsel in managing this Action, as well as the secretarial and clerical employees who work regularly with such individuals, provided however that any such in-house personnel shall execute an Acknowledgement of Protective Order, which is attached as Exhibit A to this Order, and be identified in writing to the Producing Party before accessing any Confidential Information. If the need arises, a party may replace an in-house personnel entitled to receive Confidential Information with another of its in-house personnel on a one-for-one basis, provided that any substitute in-house personnel execute an Acknowledgement of Protective Order and be identified in writing to the Producing Party prior to receiving any information designated as CONFIDENTIAL INFORMATION, and that there are no more than a total of three (3) in-house personnel for each of the parties;

ii. Outside litigation counsel of record and supporting personnel employed in the law firm(s) of outside litigation counsel of record, such as attorneys, paralegals, clerks, secretaries, contract attorneys, IT personnel, and clerical personnel;

iii. Judges, Magistrate Judges, law clerks, and other authorized personnel of the Court before which this Action is pending;

iv. Outside consultants or experts and their supporting personnel, excluding employees, officers or directors of a named party, retained by any of the parties or their counsel to consult or testify in this Action, provided that the disclosure of Confidential Information

to any such consultant or expert shall be made only after the consultant or expert has executed an Acknowledgement of Protective Order in the form of Exhibit A;

v. Authors, creators, drafters, addressees, and other recipients of DESIGNATED MATERIAL who, prior to the commencement of this Action, lawfully received or had access to the DESIGNATED MATERIAL, or anyone who received DESIGNATED MATERIAL during the course of this Action independently and outside of this Action and not in violation of this Order;

vi. Former employees of the Producing Party provided that the employee is a witness or deponent and was both listed as an author or recipient of the information, document, or tangible item and was a current employee of the Producing Party as of the date that the information, document, or tangible item was authored or received or, from the face of the document, it appears the witness or deponent had either seen or possessed the document, information, or tangible item during the time they were a current employee of the Producing Party;

vii. Litigation, trial, and information technology consultants and their supporting personnel engaged to provide services relating to document collection and processing, indexing, scanning, imaging or storage, translation, interpretation, demonstrative exhibits, graphics, charts, animations, design services, and/or non-technical trial services, provided such individuals acknowledge that they will abide by this Order by executing the attached Acknowledgement of Protective Order which is attached as Exhibit A to this Order. Where a company or firm is retained for such litigation or trial support services, it shall be sufficient for purposes of this Order that a representative of such company or firm execute the Acknowledgement of Protective Order on behalf of the company or firm. Such representative shall be responsible for ensuring that any employee, consultant, or representative of that company

or firm who receives Confidential or Highly Confidential information abides by the provisions of this Order;

viii. Licensed court reporters and videographers taking testimony involving information designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL and necessary stenographic and clerical personnel thereof;

ix. Persons who have been retained by a party to provide translation or interpretation from one language to another, provided they acknowledge that they will abide by this Order by executing the attached Acknowledgement of Protective Order which is attached as Exhibit A to this Order.

x. and

xi. Any other person authorized to receive Confidential Information by order of the Court or by written agreement of the parties.

(b) Access to information produced and designated as HIGHLY CONFIDENTIAL INFORMATION shall be available only to individuals identified in paragraphs 5(a)(ii)-(xi), any other persons authorized to receive Highly Confidential Information by written agreement of the parties, by order of the Court, or as otherwise provided in this Order.

(c) Without prior written approval of the Producing Party, no party may disclose the Protected Information of any Defendant to another Defendant. In the event one party wishes to disclose information from any Defendant to any other Defendant, the party desiring to make such disclosure shall meet and confer with the affected Defendant(s) prior to contacting the Court. If the parties are unable to agree, they shall promptly submit their dispute to the Court for resolution.

VI. CONDITIONS ON ACCESS TO CONFIDENTIAL INFORMATION

(a) Paragraph 5(a)(iv) Experts and Consultants. Prior to a party giving, showing, disclosing, making available or communicating Confidential Information or Highly Confidential Information of another party to any expert or consultant (e.g., a person or entity that conducts testing or other analysis but does not prepare an expert report) under Paragraph 5(a)(iv) above, the party shall do the following. For the avoidance of doubt, this provision does not apply to the categories of individuals listed in Paragraphs 5(a)(i)-(iii) and 5(a)(v)-(xi) above:

i. Serve notice on all other parties identifying the expert or consultant and providing a copy of the expert or consultant's current *curriculum vitae* identifying the expert or consultant's activities and job history, including a list of all publications authored in the previous 10 years and a list of cases in which the expert or consultant has given trial and/or deposition testimony in the preceding four (4) years, and past or present relationship, if any, with any parties in this Action and their affiliates.

ii. Include with such notice, a copy of the executed Acknowledgment of Protective Order, in the form shown in Exhibit A, signed by the expert or consultant and including all the information to be completed therein.

iii. The notified parties shall be entitled to object in good faith to the disclosure of Confidential Information or Highly Confidential Information to the expert or consultant within ten (10) days after receipt of the Acknowledgment of Protective Order by stating specifically in writing the reasons why such expert or consultant should not receive Confidential Information or Highly Confidential Information. If counsel for the Producing Party does not object to such disclosure within the ten-day period, any objection to such disclosure is deemed waived, except as to any basis for objection that was not known and could not reasonably have been discovered within the ten-day period.

iv. The party seeking disclosure to an objected-to expert or consultant shall attempt to resolve the objection through a meet and confer with the objecting party within five (5) days of receiving the written objection.

v. If the parties are unable to agree on disclosure to the expert or consultant, the party objecting to such expert or consultant may apply to the Court pursuant to the Court's discovery dispute procedures for an order that disclosure is improper within seven (7) days of the parties' meet and confer. The burden of establishing the validity of such written objections rests with the objecting party. If the objecting party does not apply to the Court within the prescribed period, the objection shall be deemed withdrawn.

vi. No disclosure of Confidential Information or Highly Confidential Information shall be made to the proposed expert or consultant until the time for serving objections to that expert or consultant has passed, or, in the event that a written objection is timely served and a motion to prevent disclosure is filed, until such time as the Court has made a ruling thereon, and then, only in accordance with such ruling.

vii. The filing and pendency of objections shall not limit, delay, or defer any disclosures of Confidential Information or Highly Confidential Information to persons as to whom no such objection has been made, nor shall it delay or defer any other pending discovery unless the level of confidentiality bears directly on the objecting party's ability to conduct such discovery.

(b) *Patent Prosecution.* Any attorney for or representing any Party, whether in-house or outside counsel, and any person associated with any Party and permitted to receive Confidential and/or Highly Confidential Information pursuant to Paragraph 5 herein, who obtains, receives, has access to, or otherwise learns, in whole or in part, Confidential and/or Highly

Confidential Information under this Order shall not prepare, prosecute, supervise, or substantively assist in the drafting or amending of patent claims in any U.S. or foreign patent application pertaining to migalastat, including dosage forms thereof, or the disclosed Confidential and/or Highly Confidential Information beginning on the date an individual first has access to Confidential and/or Highly Confidential Information under this Order and continuing for one (1) year after the conclusion of this Action, including any appeals. Any attorney for or representing any Party, whether in-house or outside counsel, and any person associated with any Party and permitted to receive Confidential and/or Highly Confidential Information pursuant to Paragraph 5 herein, who obtains, receives, has access to, or otherwise learns, in whole or in part, Confidential and/or Highly Confidential Information under this Order shall not amend, draft, or otherwise substantively assist in the drafting or amending of patent claims in any post-grant proceeding (e.g., reexamination, post-grant review (“PGR”) or inter partes review (“IPR”) proceedings, etc.) pertaining to migalastat, including dosage forms thereof, or the disclosed Confidential and/or Highly Confidential Information beginning on the date an individual first has access to Confidential and/or Highly Confidential Information under this Order and continuing for one (1) year after the conclusion of this Action, including any appeals. Nothing herein shall prohibit an individual from participating, supervising, or assisting with respect to any post-grant proceeding (or appeals therefrom), so long as that individual does not participate in any claim amendments. Any attorney for or representing any Party, whether in-house or outside counsel, and any person associated with any Party shall not directly or indirectly use and/or disclose Confidential and/or Highly Confidential Information to any individuals involved in drafting, amending, or prosecuting patent claims pertaining to migalastat or dosage forms thereof. The foregoing restrictions of this paragraph shall apply only to individuals, and not to the firms or organizations by which they are

employed, and shall not be imputed to any attorneys, in-house personnel, or other persons at the affected individual's firm or company. It is expressly agreed that attorneys, in-house personnel, or other persons who work on this Action who do not receive access to DESIGNATED MATERIAL by a Producing Party shall not be subject to this paragraph. For the avoidance of doubt, the restrictions under this paragraph do not otherwise prohibit involvement in prosecution a patent application, including drafting or amending claims, directed to other subject matter.

(c) *Authorization and Acknowledgment.* Counsel for the Receiving Party shall keep in his or her files a copy of each Acknowledgment of Protective Order executed by an individual required to execute an Acknowledgement prior to receipt of the Producing Party's Confidential Information or Highly Confidential Information until sixty (60) calendar days after the final termination of this Action.

VII. PROCEDURES FOR FILING PAPERS WITH CONFIDENTIAL INFORMATION

Confidential Information or Highly Confidential Information may be included with, or referred to in, papers filed with the Court where this case is now pending or in any other court only in accordance with the following procedures:

(a) Both Confidential Information and Highly Confidential Information must be filed under seal in accordance with the provisions of the Local Rules of the United States District Court for the District of Delaware and any applicable Standing Orders of this Court. Counsel for all parties shall follow all applicable local rules and customs for the Court when filing Confidential Information or Highly Confidential Information under seal.

(b) All papers filed with the Court, including but not limited to pleadings and memoranda of law, which include, in their entirety or in part, any Confidential Information or Highly Confidential Information must be filed under seal in accordance with the terms and

procedures set forth in this Order, including the procedures for filing materials set forth above in Paragraph 7(a). Counsel for the party filing papers with Confidential Information or Highly Confidential Information shall be responsible for appropriately designating the papers filed with the Court as having Confidential Information or Highly Confidential Information. Such papers shall be subject to the terms of this Order.

(c) Upon the failure of the filing party to properly designate information, any party or third party who in good faith believes that designation and filing under seal is required may move the Court to file such information under seal within fourteen (14) days of learning of the defective filing or lodging. The burden of proving that such information should be sealed shall at all times remain on the party which designated the information as DESIGNATED MATERIAL.

VIII. REDACTED FILINGS OF PAPERS WITH CONFIDENTIAL INFORMATION

Redacted versions of papers with Confidential Information or Highly Confidential Information filed under seal may be filed with the Court in accordance with normal procedures and made publicly available provided that:

(a) Confidential Information and/or Highly Confidential Information set forth in the papers is deleted or obscured in accordance with the provisions of the Local Rules of the United States District Court for the District of Delaware and any applicable Standing Orders of this Court. Counsel for all parties shall follow all applicable local rules and customs for the Court when filing redacted versions of papers with Confidential Information or Highly Confidential Information; and

(b) Redacted versions of the papers are clearly marked “Public Version Confidential Material Omitted.” Redacted versions of the papers also must clearly identify each place where information or exhibits have been deleted.

IX. UNINTENTIONAL FAILURE TO DESIGNATE

The inadvertent failure by a Producing Party to designate specific documents or materials as containing Confidential Information or Highly Confidential Information shall not be deemed a waiver in whole or in part of a claim of confidentiality as to such documents or materials. If, through inadvertence, a Producing Party provides any Confidential Information or Highly Confidential Information pursuant to this Action without designating and marking the Confidential Information as CONFIDENTIAL or HIGHLY CONFIDENTIAL, the Producing Party shall inform the Receiving Party of the confidential nature of the disclosed Confidential Information in writing within seven (7) days of the discovery of the inadvertent disclosure, and the Receiving Party shall treat the disclosed Confidential Information or Highly Confidential Information as CONFIDENTIAL or HIGHLY CONFIDENTIAL upon receipt of written notice from the Producing Party. Disclosure of such Confidential Information or Highly Confidential Information to persons not authorized to receive that material prior to receipt of the confidentiality designation shall not be deemed a violation of this Order. However, in the event the material has been distributed in a manner inconsistent with the categorical designation, the Receiving Party will take the reasonable steps necessary to conform distribution to the categorical designation, i.e., by retrieving all copies of the Confidential Information or Highly Confidential Information, or notes or extracts thereof, in the possession of the persons not authorized under this Order to possess such Confidential Information or Highly Confidential Information and advising the person to whom disclosure was made that the material is confidential and should be treated as provided in the Order.

Within seven (7) days of the notice of such inadvertent disclosure, the Producing Party shall provide properly designated information, documents, or tangible items, as applicable. Upon receipt of properly designated replacement information, documents, or tangible items, the

Receiving Party shall substitute properly designated copies for those previously received and return to outside counsel for the Producing Party or third party all such previously undesignated or improperly designated information, documents, or tangible items including all copies, or certify destruction thereof, within seven (7) days after receiving the replacement copies.

For purposes of this provision, all failures to designate that a Party claims were inadvertent shall be deemed to be inadvertent.

X. DISCLOSURE OF PRIVILEGED INFORMATION

(a) The inadvertent production or disclosure of any document or tangible thing (including information) that should have been withheld subject to a claim of attorney-client privilege or work product immunity, or other privilege or immunity, shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claims of privilege or work product immunity. This order shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(d). In the event of any such inadvertent production, the Producing Party shall send to each receiving party a written request for return of the inadvertently produced or disclosed document or thing (“Clawback Notice”) within seven (7) days after becoming aware of such inadvertent or mistaken production, which shall identify the privileged information inadvertently produced and the basis on which the privileged information should have been withheld from production. The Producing Party shall, within five (5) days of the date of the Clawback Notice, reproduce any document that is comprised only partially of privileged information with the privileged information redacted.

(b) Within seven (7) days of receiving the Clawback Notice from the Producing Party, the Receiving Party shall: (a) destroy or return to the Producing Party any documents or tangible items that the Producing Party represents are covered by a claim of attorney-client

privilege or work-product immunity, or other privilege or immunity, and were inadvertently or mistakenly produced; and (b) destroy any extra copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information, including any electronic records thereof. If the Receiving Party destroys the documents or tangible items in question, the Receiving Party shall notify the Producing Party that it has done so within the seven (7)-day window described above. The Receiving Party may retain a single copy of the documents or tangible items that the Producing Party represents are covered by a claim of privilege or immunity for the sole purpose of contesting the Producing Party's claim of privilege or immunity. The Receiving Party shall not utilize the information contained in the inadvertently produced documents or things for any purpose other than to contest the Producing Party's claim of privilege or immunity where applicable, and shall not disseminate or transmit such information.

(c) If the Receiving Party wishes to contest that any such document or thing is protected from disclosure by the attorney-client privilege, work product immunity or other privilege or immunity from discovery, it shall so notify the Producing Party in writing when the document or thing is returned to the Producing Party or destroyed ("Notice of Designation").

(d) Within five (5) days after receiving a Notice of Designation, the Producing Party shall provide to the Receiving Party for each document or thing a description of the basis for the claim of privilege or immunity.

(e) Within five (5) days after receiving such description, the Receiving Party may seek relief from the Court to compel production of such documents and things, the protection of which is still disputed, in accordance with the procedures set forth in the Court's Scheduling Order for resolution of discovery disputes. The party claiming the privilege or immunity shall have the burden of proving that such privilege or immunity exists.

(f) If the Receiving Party does not notify the Producing Party that the Receiving Party disputes the claims of attorney-client privilege or work-product immunity, or if the Court rejects any challenge by the Receiving Party to the privileged status of the inadvertent production, the Receiving Party shall destroy or return all copies of the documents or tangible items that it retained for purposes of contesting the privileged status of the inadvertent production

(g) If, in a deposition, hearing, or other proceeding the party who made the inadvertent production or disclosure makes a request on the record for return of the inadvertently produced or disclosed document or thing within a reasonably prompt period of time after recognizing that the information has been produced or disclosed, all copies of the inadvertently produced or disclosed document or thing present at the deposition, hearing, or other proceeding shall immediately be sequestered and there shall be no further use of the inadvertently produced or disclosed document or thing. For the avoidance of any dispute, the marking of an inadvertently produced or disclosed document or thing as an exhibit at deposition, hearing, or other proceeding has no bearing on the timeliness of the request for return.

The procedures set forth in this paragraph for challenging the privileged status of an inadvertent production shall not result in any waiver of the attorney- client privilege, the work product immunity, or any other privilege or immunity.

XI. USE OF DESIGNATED MATERIAL IN DEPOSITIONS, HEARINGS, OR TRIAL

Designated Material may only be used, relied upon, and referred to in any testimony or other evidence presented at any trial, hearing, or deposition in connection with this Action consistent with and under the terms of this Order, and subject to any further order of this Court regarding confidentiality, as follows:

(a) A party may examine, at a deposition, hearing or trial, persons who are authorized to receive DESIGNATED MATERIAL under the terms of this Order, to the extent that such persons are permitted access to such information under this Order, or as otherwise permitted by the Court; and

(b) A party may examine, at a deposition, hearing or trial, persons who are not authorized to receive DESIGNATED MATERIAL under the terms of this Order, so long as such examination concerns DESIGNATED MATERIAL (i) for which the Producing Party is the witness's current employer, (ii) that the witness authored or previously had access to or knowledge of, (iii) for which the witness is the Producing Party's Federal Rule of Civil Procedure 30(b)(6) deposition designee, (iv) or as otherwise permitted by this Court.

Consistent with the other provisions of this Order, when a party's or third party's DESIGNATED MATERIAL is discussed or disclosed during a deposition, the party or third party may exclude from the deposition any person not authorized under this Order to have access to the DESIGNATED MATERIAL while the DESIGNATED MATERIAL is discussed or disclosed.

XII. INFORMATION NOT COVERED BY THIS ORDER

The restrictions set forth in this Order shall not apply to information which is in the possession of or otherwise known to the Receiving Party or the public before the date of its transmission to the Receiving Party, or which lawfully comes into the possession of or becomes known to the Receiving Party or lawfully comes into the possession of or otherwise becomes known to the public after the date of its transmission to the Receiving Party, provided that such information does not come into the possession of the Receiving Party or become publicly known by any act or omission which would be in violation of this Order, a similar Order with respect to another party, or any other duty of confidentiality.

XIII. RESPONSIBILITY OF ATTORNEYS

Outside counsel of record shall be responsible for providing a copy of this Order to all persons entitled access to Confidential Information or Highly Confidential Information under Paragraph 5 and to employ reasonable measures to control duplication of, access to, and distribution of copies of materials so designated. No person shall duplicate any Confidential Information or Highly Confidential Information except, as contemplated by this Order, for use as exhibits at depositions, in connection with court filings or, as necessary, by counsel, experts or consultants approved under Paragraphs 5 and 6 for use as working copies. All copies, extracts and translations must be appropriately marked as provided by this Order.

Nothing in this Order shall bar or otherwise restrict any attorney from rendering advice to a party-client or, in the course thereof, relying upon his or her knowledge of DESIGNATED MATERIAL provided, however, that in rendering such advice the attorney shall not disclose any DESIGNATED MATERIAL to unauthorized persons.

XIV. FINAL DISPOSITION

Upon termination, settlement or final judgment of this Action including exhaustion of all appeals, the originals and all copies of Confidential Information and Highly Confidential Information shall be either destroyed or turned over to the Producing Party, or to their respective outside counsel, within sixty (60) days, except that a party is not obligated to return or destroy Confidential Information or Highly Confidential Information that may be contained on electronic back-up tapes or other archival media, which should be treated in accordance with standard retention policies, i.e., which are not retained indefinitely without being overwritten. Retained counsel also may retain pleadings, attorney and consultant work product, and depositions for archival purposes. If Confidential Information or Highly Confidential Information is destroyed

pursuant to this paragraph, outside counsel for the Receiving Party shall notify outside counsel for the Producing Party of the destruction.

XV. NO LIMITATION OF OTHER RIGHTS

This Order shall be without prejudice to the right of any party to oppose production of any information on any and all grounds other than confidentiality.

XVI. RELEASE FROM OR MODIFICATION OF THIS ORDER

This Order is entered without prejudice to the right of any party to apply to the Court at any time for additional protection, or to release, rescind, or modify the restrictions of this Order, to determine whether a particular person shall be entitled to receive any particular information or to seek relief from inadvertent disclosure of privileged or work-product information. This Order does not preclude all of the parties to this Order from entering into any stipulation (in writing or on the record) constituting a modification of this Order. On any motion seeking disclosures beyond those authorized by this Order, the burden will be on the Receiving Party to justify the disclosure.

XVII. DISCOVERY FROM THIRD PARTIES

If discovery is sought of a person not a party to this Action (third party) requiring disclosure of such third party's Confidential Information or Highly Confidential Information, the Confidential Information and/or Highly Confidential Information disclosed by any such third party will be accorded the same protection as the parties' Confidential Information/Highly Confidential Information, and will be subject to the same procedures as those governing disclosure of the parties' Confidential Information/Highly Confidential Information pursuant to this Order, provided that the third party first agrees in writing to the terms of this Order by executing the Acknowledgement of Protective Order which is attached as Exhibit A to this Order.

If, in responding to a discovery request, subpoena, or other legal process, a third party discloses DESIGNATED MATERIAL belonging to or owned by a party to this Action, the information disclosed by the third party shall be afforded the same protection as if it were received from a Producing Party under this Order. In such event, a third party, in good faith believing the information disclosed to be its DESIGNATED MATERIAL, may designate such information pursuant to the terms of this Order.

XVIII. ADMISSIBILITY

Nothing herein shall be construed to affect in any way the evidentiary admissibility of any document, testimony, or other matter at any court proceeding related to this matter. The marking of Confidential Information as CONFIDENTIAL or Highly Confidential Information as HIGHLY CONFIDENTIAL pursuant to this Order shall not, for that reason alone, bar its introduction or use at any court proceeding related to this matter pursuant to such terms and conditions as the Court may deem appropriate, consistent with the need for a complete and accurate record of the proceedings; provided, however, that every effort shall be made, through the use of procedures agreed upon by the parties or otherwise, to preserve the confidentiality of Confidential Information marked as CONFIDENTIAL or Highly Confidential Information marked as HIGHLY CONFIDENTIAL.

XIX. NON-PARTY REQUEST / SUBPOENA OF CONFIDENTIAL INFORMATION

If a Receiving Party receives a subpoena or other compulsory process from a non-party to this Order seeking production or other disclosure of a Producing Party's Confidential Information or Highly Confidential Information, that Receiving Party shall give written notice to outside counsel of record for the Producing Party within ten (10) days after receipt of the subpoena or other compulsory process identifying the specific Confidential Information or Highly Confidential

Information sought and enclosing a copy of the subpoena or other compulsory process. If written notice to the Producing Party must be provided by an earlier time to allow the Producing Party to timely seek a protective order, the Receiving Party must provide written notice by that earlier time. If the Producing Party timely seeks a protective order, the Receiving Party to whom the subpoena or other compulsory process was issued or served shall not produce the Confidential Information or Highly Confidential Information requested prior to receiving a Court order or consent of the Producing Party. In the event that Confidential Information and/or Highly Confidential Information is produced, other than by Court order, to the non-party in accordance with this provision, such material shall be treated as Confidential Information or Highly Confidential Information pursuant to this Order.

XX. UNINTENTIONAL DISCLOSURE OF CONFIDENTIAL INFORMATION

If Confidential Information, Highly Confidential Information, or any portion thereof, is disclosed by the Receiving Party, through inadvertence or otherwise, to any person or party not authorized under this Protective Order, then the Receiving Party shall use its best efforts to retrieve immediately all copies of such Confidential Information or Highly Confidential Information, and to bind such person to the terms of this Order. In such event, the Receiving Party shall also (a) promptly inform such person of all the provisions of this Order; (b) identify such person immediately to the Producing Party; and (c) request such person to execute the Acknowledgment of Protective Order in the form shown in Exhibit A.

XXI. COUNSEL'S RIGHT TO PROVIDE ADVICE

Nothing in this Order shall bar or otherwise restrict any counsel herein from rendering advice to the counsel's party-client with respect to this Action, and in the course thereof, relying upon an examination of Confidential Information or Highly Confidential Information, provided,

however that in rendering such advice and in otherwise communicating with the party-client, the counsel shall not disclose any Confidential Information or Highly Confidential Information to anyone not authorized to receive such Confidential Information or Highly Confidential Information pursuant to the terms of this Order.

XXII. DISCOVERABILITY OF EXPERT MATERIALS

Discovery of communications between counsel and any independent expert retained or specially employed by that counsel for purposes of this Action shall be limited to the factual information, analyses, documents, and/or data relied on by the expert in rendering the opinions expressed in an expert report or at trial. Except as otherwise provided herein, all communications between counsel and the expert relating to the process of preparing an expert report or developing opinions for trial, including all preliminary or draft reports, expert working papers, notes, and communications relating thereto, shall be deemed exempt from discovery and use at trial.

XXIII. NO CONTRACT

To the extent that the parties have agreed on the terms of this Order, such stipulation is for the Court's consideration and approval as an Order. The parties' stipulation shall not be construed to create a contract between the parties or between the parties and their respective counsel.

XXIV. EFFECTIVE DATE

Documents that have been produced in this case on a confidential or highly confidential basis prior to the entry of this Order shall henceforth be subject this Order.

XXV. TERMINATION

The termination of this Action shall not automatically terminate the effectiveness of this Order and persons subject to this Order shall be bound by the confidentiality obligations of this

Order until the Producing Party agrees otherwise in writing or this Court (or any other court or competent jurisdiction) orders otherwise.

XXVI. OTHER PROCEEDINGS

By entering this Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this Order who becomes subject to a motion to disclose another party's information designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL pursuant to this Order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

BARNES & THORNBURG LLP

/s/ Chad S.C. Stover

Chad S.C. Stover (No. 4919)
222 Delaware Avenue, Suite 1200
Wilmington, DE 19801
Tel: (302) 300-3474
Email: Chad.Stover@btlaw.com

John W. Cox, Ph.D.**
Christina M. Baugh**
Joshua M. Kalb**
Lauren Baker**
Anna Whitacre**
3340 Peachtree Road N.E., Suite 2900
Atlanta, GA 30326
Tel. (404) 264-4092
Email: John.Cox@btlaw.com
Email: Christina.Baugh@btlaw.com
Email: Josh.Kalb@btlaw.com
Email: Lauren.Baker@btlaw.com
Email: Anna.Whitacre@btlaw.com

SHAW KELLER LLP

/s/ Karen E. Keller

Karen E. Keller
Nathan R. Hoeschen
I.M. Pei Building
1105 N. Market Street, 12th Floor
Wilmington, DE 19801
kkeller@shawkeller.com
nhoeschen@shawkeller.com

Kurt A. Mathas
Tyree M. Petty-Williams
WINSTON & STRAWN LLP
35 West Wacker Dr.
Chicago, IL 60601-9703
kmathas@winston.com
tpettywilliams@winston.com

*Counsel for Teva Pharmaceuticals USA, Inc.
and Teva Pharmaceuticals, Inc.*

Mark C. Nelson**
2121 N. Pearl Street, Suite 700
Dallas, TX 75201
Tel: (214) 258-4140
Email: Mark.Nelson@btlaw.com

Heather B. Repicky**
One Marina Park Drive, Suite 1530
Boston, MA 02210
Tel: (617) 316-5317
Email: Heather.Repicky@btlaw.com

Josh E. Ney, Ph.D.**
1717 Pennsylvania Avenue N.W., Suite 500
Washington, DC 20006-4628
Tel: (734) 489-8004
Email: Josh.Ney@btlaw.com

** Admitted *pro hac vice*

Attorneys for Plaintiffs

KRATZ & BARRY LLP

/s/ R. Touhey Myer
R. Touhey Myer
800 N. West Street
Wilmington, DE 19801
tmeyer@kratzandbarry.com

Timothy H. Kratz
George J. Barry III
1050 Crown Pointe Parkway, Suite 500
Atlanta, GA 30338
tkratz@kratzandbarry.com
gbarry@kratzandbarry.com

Michael P. Hogan
325 Chestnut Street, Suite 883, #259
Philadelphia, PA 19106
mhogan@kratzandbarry.com

*Counsel for Aurobindo Pharma Ltd. and
Aurobindo Pharma USA, Inc.*

**PHILLIPS, MCLAUGHLIN & HALL,
P.A.**

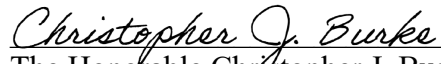
/s/ David A. Bilson
John C. Phillips, Jr.
David A. Bilson
1200 North Broom Street
Wilmington, DE 19806
jcp@pmhdelaw.com
dab@pmhdelaw.com

Keith D. Parr
Nina Vachhani
Jonathan B. Turpin
Jacob Britz
Amy M. Lange
LOCKE LORD, LLP
111 South Wacker Drive
Chicago, IL 60606
kparr@lockelord.com
nvachhani@lockelord.com
jonathan.turpin@lockelord.com
jacob.britz@lockelord.com

amy.lange@lockelord.com
Lupin_Migalastat@lockelord.com

*Counsel for Lupin Ltd. and Lupin
Pharmaceuticals, Inc.*

IT IS SO ORDERED THIS 12th day of September, 2023.



The Honorable Christopher J. Burke
United States Magistrate Judge

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AMICUS THERAPEUTICS US, LLC AND
AMICUS THERAPEUTICS, INC.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC. and
TEVA PHARMACEUTICALS, INC.;

Defendants.

C.A. No. 22-1461-CJB
ANDA CASE

(consolidated)

EXHIBIT A

**ACKNOWLEDGEMENT OF PROTECTIVE
ORDER**

I, _____ state that I have read and reviewed in its entirety the Protective Order (“Protective Order”) that has been signed and entered in this matter.

I hereby agree to be bound by and comply with the terms of the Protective Order, and not to disseminate or disclose any information subject to the Protective Order that I review or about which I am told, to any person, entity, party, or agency for any reason, except in accordance with the terms of the Protective Order.

I understand that contempt sanctions may be entered for violation of this Protective Order and further agree to submit to the jurisdiction of this Court for the purposes of enforcement of the terms of this Protective Order.

DATED this ____ day of _____, 202__

Signature